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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,766	12/29/2006	Hideki Hasegawa	43512-103808	5560
23644 7590 07/13/2010 BARNES & THORNBURG LLP P.O. BOX 2786 CHICAGO, IL 60690-2786			EXAMINER BOESEN, AGNIESZKA	
			ART UNIT 1648	PAPER NUMBER
			NOTIFICATION DATE 07/13/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No. 10/567,766	Applicant(s) HASEGAWA ET AL.	
	Examiner AGNIESZKA BOESEN	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed June 28, 2010 in response to the Office Action of February 26, 2010 is acknowledged and has been entered. Upon further consideration the finality of the Office action of February 26, 2010 is vacated and the prosecution is REOPENED. Ant inconvenience is regretted. Claims 1-10 and 15-18 are withdrawn. Claims 11-14 are under examination in this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 11-14 under 35 U.S.C. 103(a) as being unpatentable over Hilleman et al. (US Patent 3,609,092) in view of Wong et al. (Antimicrobial Agents and Chemotherapy. 1995, Vol. 39, p. 2574-2576 in IDS on 5/8/2008) **is withdrawn** in view of Applicant's arguments.

New Rejection

Claims 11-14 under 35 U.S.C. 103(a) as being unpatentable over Kedar et al. (US Patent 5,919,480) in view of de Haan et al. (Vaccine, 1995, Vol. 13, p. 155-162) and Knight et al. (Research in Veterinary Science, 1977, Vol. 23, p. 38-42 in IDS on 10/22/2008).

Kedar teaches methods of preventing influenza infection comprising administering to the nasal mucosa influenza virus subunit antigen in a physiological solution (see claims 17-20, Examples 1 and 2, and column 7, lines 39-47). Kedar teaches induction of IgG antibodies,

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however Kedar does not teach a concentration sufficient to produce secretory IgA. Kedar does not teach double-stranded RNA.

De Haan teaches methods comprising mucosally administering influenza subunit vaccine at concentration sufficient to produce secretory IgA (see Table 1 and Figure 2). De Haan teaches administering the influenza vaccine at least twice, wherein the second dose is given four days after the first immunization (see page 156 in paragraph Immunizations and sample collection). Thus de Haan teaches mucosally administering the influenza vaccine at least twice and once a week.

Knight teaches methods comprising administering double stranded RNA such as poly IC and an inactivated Newcastle disease virus. Knight teaches that poly IC has an adjuvant effect when used in the combination with Newcastle disease virus vaccines (see the entire document).

Knight teaches that combining the double stranded RNA with the aqueous vaccine before emulsification proved to be the most practical and effective method of producing the adjuvanted Newcastle disease virus vaccine (see page 41, second paragraph) and that the addition of double stranded RNA in small amounts to the inactivated Newcastle disease virus vaccine resulted in consistently higher antibody titers over a period of at least three months (see page 41, last line and page 42).

It would have been *prima facie* obvious and one would have been motivated to administer Kedar's influenza vaccine in combination with Knight's poly IC double stranded RNA wherein the vaccine is at the concentration sufficient to produce secretory IgA as taught in de Haan, because Knight teaches that poly IC has an adjuvant effect when used in the combination with virus vaccines and because Knight teaches that combining the double stranded

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RNA with the aqueous vaccine before emulsification proved to be the most practical and effective method of producing the adjuvanted Newcastle disease virus vaccine (see page 41, second paragraph) and that the addition of double stranded RNA in small amounts to the inactivated Newcastle disease virus vaccine resulted in consistently higher antibody titers over a period of at least three months (see page 41, last line and page 42).

One would have had a reasonable expectation of success to prevent influenza virus infection comprising administering the Kedar's and Knight's composition to the nasal mucosa because Kedar and de Haan teach generation of protective immune responses due to intranasal administration of influenza vaccine.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/
Examiner, Art Unit 1648